IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION MARY BETH GAST, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; and JOHNSON & JOHNSON; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.; and TEVA PHARMACEUTICAL INDUSTRIES LTD. Defendants.	MDL No. 2973 Case No. 2:22-md-02973 (BRM)(ESK) JUDGE BRIAN R. MARTINOTTI JUDGE EDWARD S. KIEL DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6 CIVIL ACTION NO.:

COMPLAINT

Plaintiff Mary Beth Gast ("Plaintiff"), by and through undersigned counsel, hereby complains against Defendants JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON

PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; and JOHNSON & JOHNSON; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.; and TEVA PHARMACEUTICAL INDUSTRIES LTD, (hereinafter collectively referred to as "Defendants"), and alleges as follows:

A. NATURE OF THE CASE

1. Elmiron®[1] is a prescription drug indicated for the relief of the pain and/or discomfort associated with interstitial cystitis (IC)—an uncommon, but painful bladder condition.

2. Upon information and belief, Defendants manufacture, promote, and sell Elmiron.

3. Upon information and belief, Defendants were and continue to be involved in and/or responsible for the post-market testing, development, labeling,[2] marketing, and/or distribution of Elmiron.

4. Upon information and belief, Defendants also had knowledge of the prior pre-market testing, development, labeling, marketing, and/or sale of Elmiron that was conducted by other entities prior to 2002.

5. During the more than two decades that Elmiron was available in the United States, Defendants knew (or should have known) of a causal association

[1] Elmiron is the brand name for pentosan polysulfate sodium or "PPS" and will be referred to throughout this First Amended Complaint simply as "Elmiron".

[2] In the context of a pharmaceutical sold in the United States, the term "label", according to Federal and FDA regulations, includes the product's package insert (and Medication Guide, if applicable), package labeling, and container label. It is this definition of "label" or "labeling" that is intended throughout this Complaint.

and/or causal relationship between Elmiron use and an increased risk of developing serious vision-related injuries, like those suffered by Plaintiff.

6. But, upon information and belief, rather than attempt to study this potential safety concern to instruct physicians on how to safely administer Elmiron therapy to avoid this risk, or to change the Elmiron drug label to warn of the risk of serious, permanent vision-related injuries, Defendants did nothing. Instead, Defendants affirmatively represented that Elmiron was a safe and effective treatment for interstitial cystitis.

7. Indeed, prior to June 2020, the U.S. label for Elmiron made no mention of risk to patients' eyes or vision.

8. As a direct result of Defendants' wrongful and tortious actions and inactions with respect to Elmiron, Plaintiff suffered and will continue to suffer serious, permanent vision-related injuries.

9. Accordingly, Plaintiff brings the instant suit, demands judgment against Defendants, and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

B. PARTIES

PLAINTIFF

10. Plaintiff is a resident of the state of Louisiana and currently resides in Houma, Louisiana.

11. Plaintiff consumed and regularly used Elmiron. As a result of her Elmiron use, Plaintiff suffered and continues to suffer severe physical and emotional

injuries including, but not limited to, toxic maculopathy.

DEFENDANTS

JANSSEN PHARMA

12. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC., ("Janssen Pharma") is a New Jersey corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

13. Upon information and belief, Defendant Janssen Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling, and/or regulatory approval of Elmiron in the state of New Jersey.

14. Upon information and belief, as part of its business, Defendant Janssen Pharma engages in the design, testing, labeling, packaging, marketing, advertising, distributing and/or selling of pharmaceutical products, including Elmiron, in the state of New Jersey.

ORTHO PHARMA

15. Defendant ORTHO-MCNEIL PHARMACEUTICALS, INC. ("Ortho Pharma") is a corporation organized under Delaware law with its principal place of business in 1000 US Highway 202, Raritan, New Jersey 08869.

16. Upon information and belief, Defendant Ortho Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the state of New Jersey.

JANSSEN R&D

17. Defendant JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC (hereinafter "Janssen R&D") is a limited liability company under the laws of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

18. Upon information and belief, Defendant Janssen R&D made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or regulatory approval of Elmiron in New Jersey.

19. Upon information and belief, Defendant Janssen R&D transacted and conducted business within New Jersey and derived substantial revenue from goods and products disseminated and used in New Jersey.

20. Upon information and belief, as part of its business, Defendant Janssen R&D is involved in the research, development, sales, and/or marketing of pharmaceutical products, including Elmiron, in New Jersey and other states.

21. Upon information and belief and at all relevant times, Defendant Janssen R&D was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Elmiron.

JOHNSON & JOHNSON

22. Defendant Johnson & Johnson (hereinafter "J&J") is a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

23. Upon information and belief, and at all relevant times, Defendants Janssen Pharma, Ortho Pharma, and Janssen R&D are wholly owned subsidiaries of Defendant J&J, with the profits of each inuring to Defendant J&J's benefit.

24. Upon information and belief, Defendant J&J and its subsidiaries are involved in the research, development, sale, and/or marketing of pharmaceutical products, including Elmiron, in the state of New Jersey, including Middlesex County.

25. Upon information and belief, Defendant J&J made consequential decisions and/or took significant actions concerning, *inter alia*, the design, marketing, promotion, labeling and/or regulatory approval of Elmiron in New Jersey.

26. Upon information and belief, Defendant J&J's decisions and/or actions with respect to Elmiron impacted, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA approval of Elmiron in the United States, including New Jersey and Middlesex County.

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.

27. Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. is a Delaware corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

28. At all relevant times, Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. regularly and continuously did business in the United States, including in the state of New Jersey. Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., individually and/or through or with its partners and joint venturers, also engaged in the design, testing, labeling, packaging, marketing, advertising, distribution, and sale of Elmiron.

TEVA PHARMACEUTICALS USA, INC.

29. Defendant TEVA PHARMACEUTICALS USA, INC. is a Delaware Corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

30. At all relevant times, Defendant TEVA PHARMACEUTICALS USA, INC. regularly and continuously did business in the United States, including in New Jersey. During these times Defendant TEVA PHARMACEUTICALS USA, INC. individually and/or through its partners and joint venturers engaged in the design, testing, labeling, packaging, marketing, advertising, distribution, and/or sale of Elmiron.

TEVA PHARMACEUTICAL INDUSTRIES LTD.

31. Defendants TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. and TEVA PHARMACEUTICALS USA, INC. are subsidiaries of parent company Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD. The global headquarters of Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD is located at 5 Basel Street, Petach Tikva 49131, Israel, and the U.S. headquarters is at 400 Interpace Parkway, #3, Parsippany, New Jersey 07054.

32. Upon information and belief, Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD., individually and/or through its partners and joint venturers, made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or regulatory approval of Elmiron.

33. Upon information and belief, Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD.'s decisions and/or actions with respect to Elmiron impacted, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA approval of Elmiron in the United States, including in New Jersey.

C. JURISDICTION AND VENUE

34. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of

interest and costs, and because Defendants are incorporated and have their principal places of business in states other than North Carolina, where the Plaintiff is a citizen.

35. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

36. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because many of the Defendants reside there, all Defendants transact and conduct business in New Jersey, and, upon information and belief, a substantial part of Defendants' acts and omissions giving rise to this Complaint occurred in New Jersey.

D. RELEVANT FACTUAL BACKGROUND

INTERSTITIAL CYSTITIS

37. Interstitial cystitis ("IC")—which is also sometimes referred to as "painful bladder syndrome"—is a chronic bladder condition in which individuals experience bladder pain, bladder pressure, pelvic pain, urinary frequency, urinary urgency, and/or nocturia.

38. According to the U.S. Centers for Disease Control, IC may impact as many as 5.1 out of every 100,000 Americans and up to 12% of U.S. women may have early symptoms of IC.[3]

39. IC is known to affect more woman than men.[4]

[3] *See* Centers for Disease Control website, "What is Interstitial Cystitis (IC)?", available online at: https://www.cdc.gov/ic/index.html.
[4] *Id.*

40. The American Urological Association (AUA) established guidelines, separating treatment options into six (6) tiers of increasingly invasive therapies for the treatment of IC. The treatments listed range from minimally invasive interventions like simple lifestyle changes to increasingly more invasive interventions like invasive diagnostic studies or surgery. The AUA recommends second-line treatment of IC to incorporate multi-modal pain management approaches including manual therapy and oral therapy options such as Elmiron. Elmiron is not the best nor the only option for treating interstitial cystitis.

41. There is no known cause of interstitial cystitis.

42. There is no known cure for interstitial cystitis and the condition is widely considered to be permanent or chronic.

FDA APPROVAL OF ELMIRON

43. On approximately June 11, 1991, Baker Norton Pharmaceuticals ("Baker Norton"), a division of Ivax Pharmaceuticals, submitted a New Drug Application ("NDA") for pentosan polysulfate sodium (NDA: 020193) (hereinafter "original NDA").

44. Pentosane polysulfate sodium is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative.

45. Pentosane polysulfate sodium is sold under the brand name Elmiron.

46. According to the FDA, "the documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical

tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."[5]

47. Upon information and belief, the FDA deemed the original NDA non-approvable in approximately 1993.

48. Upon information and belief, in response, Baker Norton submitted for FDA review additional materials in support of the NDA.

49. Again, on October 28, 1994, the FDA issued a second non-approvable letter due to insufficient clinical trial evidence to establish efficacy.

50. Upon information and belief, instead of conducting an additional clinical trial, Baker Norton analyzed the database from its Compassionate Use program, which was established in 1986. Baker Norton submitted this analysis to the FDA on August 31, 1995.

51. Upon information and belief, for this third submission of the NDA, Baker Norton relied on two clinical studies. For the first study, the FDA noted that the study indicated a statistically significant treatment effect for only two of six identified efficacy endpoints: (1) the patient's evaluation of bladder pain, and (2) the investigator's evaluation of overall improvement. The FDA also noted that one investigator influenced the results. The second clinical trial was an unblinded retrospective analysis of 2,499 patients, mostly women, in the Elmiron Compassionate Use program. The percentage of patients reporting improvement in

[5] *See* FDA Website, "New Drug Application (NDA)", available online at: https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

pain after three months of treatment was 61% but dropped to 13% after six months of treatment.

52. On September 26, 1996, the FDA approved the NDA for Elmiron for relief of pain or discomfort associated with IC.

53. The proposed label, approved by the FDA, included a Package Insert directed at physicians and other healthcare providers, as well as a Medication Guide directed at patients.

54. Beginning in approximately 1996, when Elmiron was first approved by the FDA, neither its Package Insert nor its Medication Guide contained any warnings or information regarding the risk of serious visual complications including, but not limited to, pigmentary maculopathy.

55. In short, the Elmiron labeling contained no warnings related to the risk of serious vision-related injuries caused by continued Elmiron use.

HISTORY OF ELMIRON NDA AND OWNERSHIP

56. Upon information and belief, from approximately 1996, when the NDA was approved, until approximately 1997, Baker Norton owned the trademark for Elmiron.

57. Upon information and belief, Alza Corporation ("Alza") is a wholly owned subsidiary of Johnson & Johnson.

58. Upon information and belief, Alza held the NDA from approximately April 1998 until August 2002.

59. Upon information and belief, Alza is involved in the research, development, sales, and marketing of pharmaceutical products, including Elmiron.

60. Upon information and belief, Alza advertised, promoted, marketed, sold, and distributed Elmiron.

61. Upon information and belief, in approximately 2005 Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., purchased Ivax Pharmaceuticals.

62. Upon information and belief, as part of that transaction, Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., purchased the assets and liabilities of Ivax Pharmaceuticals, including, but not limited to, Baker Norton.

63. Upon information and belief, Elmiron is a registered trademark of Teva Branded Pharmaceutical Products R&D, Inc., Teva USA, and/or Teva Pharmaceuticals, Inc., under license to Defendant Janssen Pharma.

64. Alternatively, upon information and belief, Elmiron is a registered trademark of Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, and/or ABC Corporation 1-20.

65. Upon information and belief, from approximately August 2002 until August 2004, Defendant Janssen R&D held the NDA for Elmiron.

66. Upon information and belief, from July 2004 until August 2008, Defendant Ortho Pharma held the NDA for Elmiron.

67. Upon information and belief, since August 2008 Janssen Pharma has held the NDA for Elmiron and continues to manufacture, sell, and/or distribute Elmiron in the United States.

68. Alternatively, upon information and belief, since approximately 1997 Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, and/or ABC Corporation 1-20 have held the NDA for Elmiron and continue to manufacture, sell, and/or distribute Elmiron in the United States.

69. There is no generic, non-bioequivalent form of Elmiron sold in the United States.

70. Upon information and belief, given the chronic and permanent nature of IC, Defendants anticipated (or reasonably should have anticipated), that patients taking Elmiron would likely do so indefinitely.

71. Upon information and belief, sales of Elmiron generate approximately $150M in annual revenue in the United States.

72. Elmiron was the first oral medication approved for use to relieve bladder pain or discomfort associated with IC.

DEFENDANTS' INDIFFERENCE TO INCREASING SAFETY CONCERNS

73. From approximately 1997 to the present, Defendants received multiple Adverse Event Reports ("AER") from medical professionals concerning Elmiron. These AERs included serious visual complications believed to be associated with

Elmiron use ranging from retinal hemorrhage to macular degeneration to, even, unilateral blindness.

74. Indeed, the reports of serious visual complications were not unique to the United States and, upon information and belief, serious visual complications were reported to Defendants and recorded in other AER databases around the world where Elmiron was sold, like EudraVigilance—the European Medicines Agency's ("EMA") adverse event database.

75. It is widely recognized and accepted in the pharmaceutical industry that reported AERs represent only a small fraction of adverse events associated with and/or caused by a particular drug.

76. More recently, since approximately 2018 outside, independent studies and reports documented in medical literature raise similar concerns regarding Elmiron's safety and propensity for causing serious visual complications including, but not limited to, pigmentary maculopathy.

77. In approximately May 2018, the Emory Eye Center in Atlanta, Georgia published a case study of six adult patients who each had a long history of Elmiron use. The Emory physicians observed and documented significant pigmentary maculopathy in all six patients.

78. In approximately May 2019, the Emory Eye Center published a further case study of ten patients. The doctors reported that over the last four years, patients

who did not treat IC with pentosane polysulfide sodium (Elmiron) did not experience pigmentary maculopathy.

79. The first clinical population-based study came from Kaiser Permanente in 2019, in which Kaiser Permanente reviewed the medical records of 4.3 million of its patients. This study identified 140 patients who had taken an average of five thousand Elmiron pills over fifteen years. The researchers examined 91 of these patients and found that about 25% of those taking Elmiron for five years or longer developed significant damage to the retina. The study also revealed that eye damage increased with the quantity of Elmiron intake.

80. The Kaiser Permanente research was presented at "AAO 2019"—the 2019 annual meeting of the American Academy of Ophthalmology at Moscone Center, San Francisco.

81. A Harvard Medical School case study also published in 2019 examined a female with a history of eighteen years of Elmiron use at a low dose of 200mg/day. She initially presented with symptoms that included blurry vision, difficulty seeing at night, and pigmentary changes in the retina. Two years later, she returned for evaluation and her eye examination revealed more extensive eye damage consistent with pigmentary maculopathy. The Harvard physicians concluded that long-term Elmiron use results in progression of pigmentary maculopathy, even if the drug is stopped.

82. A study published in April 2020 by the Canadian Ophthalmological Society concluded, *inter alia*, the prevalence of Elmiron-induced macular toxicity posed a "significant risk" to patients taking Elmiron.

83. In July 2020, researchers at Emory and other institutions published a retrospective case series to evaluate the disease course of pigmentary maculopathy associated with Elmiron after drug cessation. Imaging confirmed expansion of the affected areas of the retina over time and even atrophy encroaching on the foveal center. This indicates that pigmentary maculopathy continues for at least ten years after drug cessation.

DEFENDANTS WARNED ABROAD, BUT NOT IN THE UNITED STATES

84. Upon information and belief, beginning in approximately 2019, Defendants took steps to warn consumers and physicians in other countries of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron.

85. For instance, in approximately September of 2019, Defendants revised the Elmiron label in Canada to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron, as follows:

> **Ophthalmologic**
>
> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early

> detection of pigmentary maculopathy, particularly those with long term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

86. Likewise, in approximately 2019, Defendants agreed with an EMA Committee's recommendation that Elmiron's label be changed to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with long-term use of Elmiron.

87. The Elmiron label in EMA countries now warns:

> All patients should have an ophthalmologic examination after 6 months of use of PPS for early detection of pigmentary maculopathy, and, if there are no pathologic findings, regularly after 5 years of use (or earlier, in case of visual complaints). However, in case of relevant ophthalmologic findings, a yearly examination should be conducted. In such situations, treatment cessation should be considered.

88. The Elmiron label used in EMA countries further admits that eye disorders, like pigmentary maculopathy, are "uncommon" undesirable effects of the medication.

89. In approving these changes to the Elmiron label, the EMA Committee for Medicinal Products for Human Use (CHMP) created a report which, upon information and belief, Defendants received. The CHMP report noted that a warning regarding ophthalmological side effects of Elmiron was needed, in part, because pigmentary maculopathy "might not be easily recognized by the urology community".

DEFENDANTS HAD A DUTY TO PROTECT U.S. CONSUMERS, BUT DID NOT

90. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

91. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate for as long as the drug remained available for sale in the United States.

92. At all relevant times Defendants had a responsibility, after approval of the Elmiron NDA, to conduct post-marketing surveillance and continue to study the safety and efficacy of Elmiron for as long as the drug remained available for sale in the United States.

93. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

94. Upon information and belief, by approximately 2001 Defendants had reasonable evidence of a causal association between serious vision-related injuries and Elmiron use.

95. Upon information and belief, by approximately 2001 a reasonable pharmaceutical company would have understood the existence of a causal association between serious vision-related injuries and Elmiron use.

96. Upon information and belief, by approximately 2001 Defendants learned Elmiron use could cause serious vision-related injuries.

97. Upon information and belief, by approximately 2001 a reasonable pharmaceutical company would have understood the existence of a causal association

between serious vision-related injuries and Elmiron use.

98. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations concerning the safety and efficacy of Elmiron. This withheld and/or misrepresented information included, but was not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries because of their Elmiron use. Such information was material and relevant to the risk of patients like Plaintiff developing serious vision-related injuries because of taking Elmiron.

99. Upon information and belief, despite understanding Elmiron could cause vision-related injuries, Defendants knowingly withheld and/or misrepresented information concerning the safety and efficacy of Elmiron. This withheld and/or misrepresented information included, but was not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries because of their Elmiron use. Such information was required to be submitted under FDA NDA regulations and material and relevant to the risk of patients like Plaintiff developing serious vision-related injuries because of taking Elmiron.

100. Accordingly, Defendants are liable to Plaintiff for punitive damages.

HOW DEFENDANTS' MISCONDUCT ENDANGERED U.S. CONSUMERS

101. Upon information and belief, had Defendants exercised reasonable care

in testing and studying Elmiron prior to seeking FDA approval, they would have discovered that long-term Elmiron use can cause serious visual injuries including, but not limited to, pigmentary maculopathy.

102. Upon information and belief, despite understanding patients taking Elmiron would likely remain on the medication for long periods of time, Defendants failed to test and study the long-term safety and efficacy of the drug prior to seeking FDA approval.

103. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron's long-term effects prior to seeking FDA approval, they would have discovered that long-term Elmiron use can cause serious visual injuries, including, but not limited to, pigmentary maculopathy.

104. Upon information and belief, despite post-approval adverse event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Elmiron, particularly in patients who used the drug for long periods of time.

105. Upon information and belief, from the date all Defendants received FDA approval to market Elmiron in the United States, Defendants made, distributed, marketed, and sold Elmiron without providing adequate warning to Plaintiff's prescribing physicians or Plaintiff that Elmiron could cause retina damage in patients who used it. Further, Defendants failed to adequately conduct proper testing and studies with respect to retina damage and Elmiron use.

106. Upon information and belief, Defendants concealed and/or failed to completely disclose their knowledge that Elmiron was associated with and/or could cause retina damage as well as their knowledge that they had failed to fully test and/or study said risk.

107. Upon information and belief, Defendants ignored the association between the use of Elmiron and the risk of developing permanent and disfiguring visual complications, including, but not limited to, pigmentary maculopathy and retina damage.

108. Upon information and belief, Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding the true risk of retina damage from Elmiron, and similar efficacy compared to less potent products.

109. Upon information and belief, all Defendants failed to provide adequate instructions to U.S. healthcare professionals and patients regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

110. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

111. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians

and Plaintiff, that the risk of potentially serious visual complications increases the longer a patient uses Elmiron.

112. Upon information and belief, all Defendants failed to warn and/or provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop taking Elmiron if potentially serious visual complications developed while using Elmiron.

113. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of retina damage to patients taking Elmiron compared to other similarly effective pharmaceuticals.

114. Defendants' failures to provide adequate instructions and/or disclose information regarding the failure to adequately test and study Elmiron for the risk of serious visual complications further rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

115. Despite AERs from healthcare professionals and consumers around the world, from approximately 1997 until approximately September 2019 Elmiron never contained a warning, in any country or market, of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

THE FIRST ELMIRON U.S. LABEL CHANGE

116. From when Elmiron was first sold in the United States until June 16, 2020, Defendants did not warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications associated with long-term Elmiron use, including, but not limited to, pigmentary maculopathy.

117. Indeed, from when Elmiron was first sold in the United States until June 16, 2020, upon information and belief, Defendants made no attempt to warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

118. Only beginning on June 16, 2020, did Defendants' Elmiron label contain the following language as to the risk of serious, vision-related complications:

> **WARNINGS**
>
> **Retinal Pigmentary Changes**
> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor.
>
> Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of

> hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

119. Upon information and belief, Defendants never made efforts to warn U.S. healthcare providers directly using a "Dear Doctor" or "Dear Healthcare Provider" letter to inform healthcare providers of the changes in the Elmiron label or of the risk of serious, vision-related complications caused by continued Elmiron use.

120. By contrast, in Canada on December 15, 2020, Defendants issued a letter to "[h]ealthcare professionals including urologists, urogynecologists, ophthalmologists, optometrists, family physicians, and pharmacists," warning that Elmiron can cause serious vision-related injuries, including pigmentary maculopathy and noting that these injuries may be "irreversible" and that "changes [in vision] may progress even after cessation of [Elmiron] therapy."

121. The December 15 letter was signed by the Vice President, Regulatory, Quality, Risk Management and Drug Safety for Janssen, Inc., which is a subsidiary of Defendant J&J.

E. PLAINTIFF'S USE OF ELMIRON

122. Upon information and belief, at the direction of her physician, Plaintiff

began taking Elmiron continuously and daily from approximately 1996 to 2021 for the treatment of her IC-related pain.

123. Upon information and belief, in approximately August 2021, Plaintiff was diagnosed with toxic maculopathy caused by her use of Elmiron.

124. It was within one year of the date of the filing of this Complaint that Plaintiff first knew, or had any reason to know, that Plaintiff's vision-related injuries including, but not limited to, toxic maculopathy could have been caused by Elmiron.

125. As a direct result of her consistent, long-term exposure to Elmiron, Plaintiff suffered vision-related injuries.

126. Because of Defendants' actions and inactions with respect to Elmiron, Plaintiff has suffered and will continue to suffer serious vision-related injuries, as well as other personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and other economic losses, including past and future medical expenses.

127. By reason of the forgoing acts and omissions, Plaintiff has suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm.

128. Plaintiff accordingly seeks damages associated with these injuries.

129. Plaintiff would not have used Elmiron had the Defendants properly disclosed the risks associated with its use.

130. Plaintiff's injuries could have been avoided or would have been less

severe if Defendants properly disclosed the risks associated with Elmiron use.

131. Despite diligent investigation by Plaintiff into the cause of these injuries, including consultations with medical providers, the nature of Plaintiff's injuries and damages and their relationship to Elmiron was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

132. Defendants willfully, wantonly, intentionally conspired, and acted in concert to withhold information from Plaintiff, Plaintiff's healthcare providers, and the public concerning the known hazards associated with the use of and exposure to Elmiron, particularly over extended periods of time.

133. Defendants willfully, wantonly, intentionally conspired, and acted in concert to withhold safety-related warnings from Plaintiff, Plaintiff's family members, and the public concerning the known hazards associated with the use of and exposure to Elmiron, particularly over extended periods of time.

134. Defendants willfully, wantonly, intentionally conspired, and acted in concert to withhold instructions from the Plaintiff, Plaintiff's family members, and the public regarding how to identify, mitigate, and/or treat known hazards associated with the use of and exposure to Elmiron, particularly over extended periods of time.

135. Defendants willfully, wantonly, intentionally conspired, and acted in concert to ignore relevant safety concerns and deliberately not study the long-term

safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

136. Defendants failed to disclose a known defect of Elmiron and instead affirmatively misrepresented that Elmiron was safe for its intended use. Defendants disseminated labeling, marketing, promotion, and/or sales information to Plaintiff, her healthcare providers, and the public regarding the safety of Elmiron knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Elmiron use. They did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

137. Further, Defendants actively concealed the true risks associated with the use of Elmiron, particularly relating to the risk of serious vision-related injuries, by affirmatively representing in numerous communications (including, but not limited to, the Package Insert and Medication Guide) that there were no warnings required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with Elmiron use. Defendants sent these communications to the public, including Plaintiff and Plaintiff's healthcare providers.

138. Due to the absence of any warning by Defendants as to the significant health and safety risks posed by Elmiron, Plaintiff was unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

139. Due to the absence of any instructions for how to identify and/or monitor

Elmiron patients for potential vision-related complications, Plaintiff was unaware Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

140. Due to the absence of any instructions for how to safely discontinue the use of Elmiron, should vision-related complications occur, Plaintiff (and her physicians) were unaware of how to safely stop using Elmiron.

141. Given Defendants' deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Elmiron, Defendants are estopped from relying on any statute of limitations defenses.

COUNT I: STRICT LIABILITY — DEFECTIVE DESIGN AND INADEQUATE TESTING

142. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

143. At all times relevant herein, Defendants placed Elmiron into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products could be safely used for their intended purpose. Insofar as Elmiron could not be used safely without the unreasonable risk of harm, it was ineffective for the purpose for its intended use of the treatment of IC-related pain.

144. Defendants were the designers, manufacturers, and suppliers of Elmiron and are strictly liable to Plaintiff for designing, manufacturing, distributing,

marketing, selling, and placing it into the stream of commerce.

145. The Elmiron manufactured, designed, marketed, and supplied by Defendants was defective in design, manufacture, and/or formulation to such a degree that when it left Defendants' control, the harm of said product outweighed any benefit derived therefrom, which rendered it inherently dangerous and/or defective and caused serious harm to Plaintiff.

146. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective in design or formulation to such a degree that when it left the control of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

147. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate pre-market and post-market testing.

148. At all times relevant hereto, Defendants encouraged the use of Elmiron as a superior form of treatment for IC, despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendants' widespread promotional activity, physicians began commonly prescribing Elmiron as a safe and effective treatment for IC-related pain.

149. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

150. A reasonable pharmaceutical company would understand that reported

AERs represent only a small fraction of adverse events caused by a particular drug.

151. Upon information and belief, Defendants failed to act as a reasonable pharmaceutical company would in failing to adequately monitor, track, and analyze AERs to better understand what causal role, if any, Elmiron use played in the injuries suffered by Elmiron patients.

152. A reasonable pharmaceutical company would continue to study a drug even after it was commercially available for sale to distinguish between undesirable effects caused by the drug and undesirable effects associated with the drug.

153. Upon information and belief, Defendants failed to act as a reasonable pharmaceutical company would in failing to continue to study Elmiron, after it was commercially available for sale, to distinguish between undesirable effects caused by the drug and undesirable effects simply associated with the drug.

154. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, injuries that required medical treatment and will require ongoing medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

155. Alternatively, the Elmiron designed, marketed, manufactured, and supplied by Defendants was defective in design for the intended patient population due to the low bioavailability of the drug.

156. Alternatively, Elmiron that was manufactured, marketed, supplied, and sold by Defendants and prescribed to and used by Plaintiff was defective in design, manufacture, or formulation to such a degree that when it left the hands of the manufacturer, supplier, and/or seller, it was more dangerous that an ordinary consumer would expect and more dangerous than other methods of treatment for IC-related pain.

157. Defendants willfully, wantonly, intentionally conspired, and acted in concert to ignore relevant safety concerns, including adverse event reports both in the United States and around the world where Elmiron was sold. Further, Defendants deliberately chose to not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

158. Defendants improperly, negligently, falsely, and deceptively misrepresented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Elmiron from the FDA. Had the FDA known of such facts, Elmiron would have never been approved and no physician would have been able to prescribe Elmiron to Plaintiff.

159. Defendants improperly, negligently, falsely, and deceptively misrepresented or knowingly omitted, suppressed, and/or concealed material facts regarding the safety and efficacy of Elmiron from the FDA. Had the FDA known of such facts, Elmiron would have never been approved with the warnings and instructions for use that accompanied Elmiron and were provided to prescribing

physicians and the public, and Elmiron would not have been prescribed to and used by Plaintiff.

160. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, information that was material and relevant to the harm in question, no statutory presumptions in favor of Defendants are warranted.

COUNT II: STRICT LIABILITY — FAILURE TO WARN

161. Plaintiff incorporates by reference each preceding paragraph as if fully set forth herein and further alleges as follows:

162. At all relevant times hereto, Defendants advertised and promoted the use of Elmiron as a safe method of treatment for IC despite the lack of adequate testing for its safety and efficacy. Defendants also advertised and promoted Elmiron use after it knew or reasonably should have known that Elmiron suffered from a design and/or manufacturing flaw.

163. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

164. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events caused by a particular drug.

165. Upon information and belief, Defendants failed to act as a reasonable pharmaceutical company would in failing to adequately monitor, track, and analyze

AERs to better understand what causal role, if any, Elmiron use played in the injuries suffered by Elmiron patients.

166. A reasonable pharmaceutical company would have recognized the connection between vision-related injuries and Elmiron use and would have changed the Elmiron label to reflect, at a minimum, that Elmiron use was associated with serious, vision-related complications.

167. Upon information and belief, Defendants failed to act as a reasonable pharmaceutical company would by failing to timely recognize the connection between vision-related injuries and Elmiron use.

168. Upon information and belief, Defendants failed to act as a reasonable pharmaceutical company would and failed to timely change the Elmiron label to reflect, at a minimum, that Elmiron use was associated with serious, vision-related complications.

169. Despite the existence of evidence showing the use of Elmiron was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Elmiron. Defendants instead deceived the medical community and public at large, including all potential users of Elmiron, by promoting it as a safe and effective treatment for IC when in fact it was plainly unsafe and alternative, safer IC treatment methods existed.

170. Elmiron designed, marketed, manufactured, and/or supplied by

Defendants was defective due to inadequate warnings and/or instructions because Defendants knew or should have known that Elmiron created, among other things, a significantly increased risk of permanent and disfiguring eye damage. Defendants failed to adequately warn of this risk and its severity, resulting in harm to Plaintiff.

171. Defendants failed to warn physicians and users of Elmiron of the dangers and adverse side effects.

172. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature. These injuries required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT III: NEGLIGENT DESIGN

173. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

174. Defendants had a duty to exercise reasonable and ordinary care and properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that Elmiron was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

175. Instead, Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Elmiron, including the Elmiron used by Plaintiff, in a defective and unreasonably dangerous condition, and in doing so breached this duty.

176. Defendants expected Elmiron to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

177. At all times relevant hereto, Defendants' Elmiron was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

178. At all times relevant to this action, Elmiron, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed,

sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

i. When placed in the stream of commerce, Elmiron contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

ii. When placed in the stream of commerce, Elmiron was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with treatment for the relief of bladder pain or discomfort associated with interstitial cystitis;

iii. Elmiron was insufficiently tested;

iv. Elmiron caused harmful side effects that outweighed any potential utility;

v. Defendants were aware at the time Elmiron was marketed that ingestion of Elmiron would result in an increased risk of retinal pigmentary changes and other injuries;

vi. Elmiron was subject to inadequate post-marketing surveillance; and/or

vii. There were safer alternative designs and formulations that were not

utilized.

179. Elmiron was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

180. Elmiron, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with Elmiron design or formulation.

181. Elmiron, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other treatments for the relief of bladder pain or discomfort associated with interstitial cystitis and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

182. At all times relevant to this action, Defendants knew or had reason to know that Elmiron was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

183. When Defendants placed Elmiron into the stream of commerce, they knew it would be prescribed for the relief of bladder pain or discomfort associated

with interstitial cystitis, and they marketed and promoted Elmiron as safe for the relief of bladder pain or discomfort associated with interstitial cystitis.

184. Plaintiff was prescribed, purchased, and used Elmiron. Plaintiff used Elmiron for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

185. Neither Plaintiff nor her health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Elmiron before Plaintiff's ingestion of Elmiron.

186. The harm caused by Elmiron far outweighed its benefit, rendering Elmiron more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Elmiron to make it less dangerous. When Defendants designed Elmiron, the state of the industry's scientific knowledge was such that a less risky design was attainable.

187. At the time Elmiron left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or intended function of Elmiron. This was demonstrated by the existence of other treatments for the relief of bladder pain or discomfort associated with interstitial cystitis that had a more established safety profile and a considerably lower risk profile.

188. Defendants' defective design of Elmiron was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Elmiron. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Elmiron.

189. The defects in Elmiron were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

190. Due to the unreasonably dangerous condition of Elmiron, Defendants are liable to Plaintiff.

191. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Elmiron, including Plaintiff, with knowledge of the safety problems associated with Elmiron, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

192. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered profound injuries that are permanent and continuing in nature. These injuries required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT IV: NEGLIGENT FAILURE TO WARN

193. Plaintiff repeats, reiterates, and incorporates by reference every allegation of this Complaint contained in each of the foregoing paragraphs.

194. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Elmiron. Through that conduct, Defendants knowingly and intentionally placed Elmiron into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, who ingested it.

195. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Elmiron into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Elmiron to the FDA, health care professionals,

Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of Elmiron.

196. Defendants expected Elmiron to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff and her prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

197. Elmiron, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

198. Elmiron was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. Elmiron contained no warnings to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with Elmiron, including the development of Plaintiff's injuries.

199. This defect caused serious injury to Plaintiff who used Elmiron for its intended purpose and in a reasonably anticipated manner.

200. At all times herein mentioned, Defendants had a duty to exercise reasonable and ordinary care and properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such

other steps as are necessary to ensure Elmiron did not cause users to suffer from unreasonable and dangerous risks.

201. Defendants instead unreasonably labeled, distributed, and promoted Elmiron without any warnings as to the risk of vision-related complications, and in doing so breached this duty.

202. Defendants also had a continuing duty to exercise reasonable and ordinary care and warn Plaintiff of the dangers associated with Elmiron.

203. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

204. Plaintiff could not have discovered any defects in Elmiron through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

205. Defendants were aware of the probable consequences of the aforesaid conduct.

206. Despite the facts that Defendants knew or should have known that Elmiron caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Elmiron, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their

patients.

207. Elmiron, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

208. Each of the Defendants knew or should have known that the Elmiron label contained no warnings and, thus, was inadequate because it failed to communicate adequate information regarding the dangers and safe use of Elmiron, particularly taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug.

209. Further, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for the relief of bladder pain or discomfort associated with interstitial cystitis.

210. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

i. Disseminated information that was inaccurate, false, and

misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Elmiron;

ii. Continued to aggressively promote Elmiron even after they knew or should have known of the unreasonable risks from use;

iii. Failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Elmiron and the comparative severity of such adverse effects;

iv. Failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Elmiron's capacity to cause its users to suffer retinal pigmentary changes;

v. Failed to adequately warn users, consumers, and physicians about the need to perform initial and periodic retinal examinations; and

vi. Overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Elmiron.

211. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Elmiron.

212. Due to these deficiencies and inadequacies, Elmiron was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

213. Had Defendants properly disclosed and disseminated the true risks associated with Elmiron, Plaintiff would have avoided the risk of developing toxic maculopathy caused by Elmiron as alleged herein.

214. The Defendants are liable to Plaintiff for injuries caused by Defendants' negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Elmiron and the risks associated with its use.

215. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered profound injuries that are permanent and continuing in nature. These injuries required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble

damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT V: NEGLIGENCE

216. Plaintiff repeats, reiterates, and incorporates by reference every allegation of this Complaint contained in each of the foregoing paragraphs.

217. Defendants had a duty to exercise reasonable and ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of Elmiron into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

218. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Elmiron into interstate commerce in that Defendants knew or should have known that using Elmiron created a high risk of unreasonable, dangerous side effects, including but not limited to retinal pigmentary changes, vision changes, and potentially irreversible vision damage, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

219. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

i. Manufacturing, producing, promoting, formulating, creating, and/or designing Elmiron without thoroughly testing it;

ii. Manufacturing, producing, promoting, formulating, creating, and/or designing Elmiron without adequately testing it;

iii. Not conducting sufficient testing programs to determine whether or not Elmiron was safe for use, in that Defendants herein knew or should have known that Elmiron was unsafe and unfit for use by reason of the dangers to its users;

iv. Selling Elmiron without making proper and sufficient tests to determine the dangers to its users;

v. Failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Elmiron;

vi. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use Elmiron;

vii. Failing to test Elmiron and/or failing to adequately, sufficiently and properly test Elmiron;

viii. Advertising and recommending the use of Elmiron without sufficient knowledge as to its dangerous propensities;

ix. Representing that Elmiron was safe for use for its intended purpose, when it was, in fact, unsafe;

x. Representing that Elmiron had equivalent safety and efficacy as other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis;

xi. Designing Elmiron in a manner which was dangerous to its users;

xii. Manufacturing Elmiron in a manner which was dangerous to its users;

xiii. Producing Elmiron in a manner which was dangerous to its users;

xiv. Assembling Elmiron in a manner which was dangerous to its users;

xv. Concealing information from Plaintiff in knowing that Elmiron was unsafe, dangerous, and/or non-conforming with FDA regulations;

xvi. Improperly concealing and/or misrepresenting information from Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Elmiron compared to other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis.

220. Defendants underreported, underestimated, and downplayed the serious vision-related injuries associated with Elmiron use.

221. Defendants negligently compared the safety risk and/or dangers of Elmiron with other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis.

222. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of Elmiron in that they:

i. Failed to use due care in designing and manufacturing Elmiron so as to avoid the aforementioned risks to individuals when Elmiron was used for the relief of bladder pain or discomfort associated with interstitial cystitis;

ii. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Elmiron;

iii. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Elmiron;

iv. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Elmiron;

v. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

vi. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Elmiron;

vii. Failed to warn Plaintiff, prior to actively encouraging the sale of Elmiron, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

viii. Were otherwise careless, unreasonable, given the circumstances, and/or negligent.

223. Even though Defendants knew or should have known that Elmiron caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Elmiron to consumers, including Plaintiff.

224. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury because of Defendants' failure to exercise ordinary care.

225. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and will continue to suffer.

226. As a result of the foregoing acts and omissions, Plaintiff suffered profound injuries that are permanent and continuing in nature. These injuries required medical treatment and will require on-going medical treatment, resulting

in significant past and future medical expenses. Additionally, Plaintiff suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

227. Plaintiff suffered damages in an amount to be determined at trial.

COUNT VI: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

228. Plaintiff repeats, reiterates, and incorporates by reference every allegation of this Complaint contained in each of the foregoing paragraphs.

229. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et. seq*., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise…" and declares such acts or practices as unlawful.

230. Upon information and belief, as discussed herein, Defendants, at all relevant times, made false and misleading representations concerning Elmiron.

231. Upon information and belief, as discussed herein, Defendants, at all relevant times, omitted material facts in their marketing, promotion, and sale of Elmiron.

232. More specifically, for example, Defendants communicated the purported benefits of Elmiron while failing to disclose the serious and dangerous side

effects related to the use of Elmiron, with the intent that consumers, including Plaintiff, and her healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Elmiron, respectively.

233. Such representations and omissions violated New Jersey Consumer Fraud Act.

234. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use Elmiron, causing severe injuries and damages as previously described herein.

235. Additionally, and in the alternative, as a result of violating the New Jersey Consumer Fraud Act, Defendants also caused Plaintiff's injuries to go undetected for a period of time, causing them to be more severe than they otherwise would have been, if Plaintiff had been given appropriate safety information and been advised to seek medical treatment and/or intervention sooner.

236. Plaintiff is, therefore, entitled to damages under the New Jersey Consumer Fraud Act.

PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES

237. The acts and omissions of Defendants described above consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

238. Defendants' actions amounted to actual malice or reckless indifference

to the likelihood of harm associated with their acts and omissions.

239. Defendants misled both the medical community and the public, including Plaintiff and Plaintiff's physicians, by making false representations about the safety and effectiveness of Elmiron and by failing to provide adequate instructions and training concerning its use.

240. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Elmiron despite available information demonstrating that drug could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells, cause potentially irreversible vision issues and retinal harm, cause PPS toxicity and/or PPS maculopathy, cause irreversible damage to a user's vision, eyes, and retinas, and cause maculopathy.

241. Defendants were or should have been in possession of evidence demonstrating that Elmiron use could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells, cause potentially irreversible vision issues and retinal harm, cause PPS toxicity and/or PPS maculopathy, cause irreversible damage to a user's vision, eyes, and retinas, and cause maculopathy. Nevertheless, Defendants continued to market Elmiron by providing false and misleading information regarding its safety and effectiveness.

242. Defendants failed to provide warnings that would have dissuaded health

care professionals from using Elmiron, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Elmiron.

243. As a proximate result of Defendants' acts and omissions, Plaintiff suffers from toxic maculopathy and other vision-related symptoms resulting from Plaintiff's prolonged and continuous ingestion of Elmiron.

244. As a result of Plaintiff's injuries, Plaintiff endured substantial pain and suffering, incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

245. Plaintiff suffered and will continue to suffer economic loss.

246. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

247. Plaintiff's injuries and damages are severe, permanent, and ongoing. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

248. Defendants' conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

249. Consequently, Defendants is liable for punitive damages in an amount to be determined by the jury.

ACCORDINGLY, Plaintiff is entitled to recover punitive damages.

PRAYER FOR RELIEF

250. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate Plaintiff:

a. Medical Expenses;

b. Physical Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort of Plaintiff;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre- and Post-Judgment Interest;

g. Exemplary and Punitive Damages;

h. Treble Damages;

i. Reasonable and Necessary Attorneys' Fees and Costs, and

j. Such other relief to which Plaintiff may be justly entitled.

WHEREFORE, Plaintiff respectfully prays of this Court and demands from Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law including, but not limited to, past and future medical expenses, lost wages in the past, loss of wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, past and future physical impairment, loss of enjoyment of life, and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants

and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) pre-judgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Dated: August 2, 2022

Respectfully submitted,

/s/ Emily T. Acosta
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